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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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11/16/2005

Tim Cheeseright

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RENNER OTTO BOISSELLE & SKLAR, LLP
1621 EUCLID AVENUE
NINETEENTH FLOOR
CLEVELAND, OH 44115

EXAMINER

SKOWRONEK, KARLHEINZ R

ART UNIT

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1631

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/526,335	Applicant(s) CHEESERIGHT ET AL.	
	Examiner KARLHEINZ R. SKOWRONEK	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Status

Claims 1-13 and 16 are pending.

Claims 14 and 15 are cancelled.

Claims 1-13 and 16 have been examined.

Claims 1-13 and 16 are rejected.

Priority

This application was filed on 16 November 2005 and is the 35 USC 371 National phase application of International Application PCT/GB03/03605 filed on 18 August 2003.

Claim Rejections - 35 USC § 101

Response to Arguments

The rejection of claim 16 is withdrawn in view of the amendment to the claim.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following rejection is maintained from the previous action.

Claims 1-12 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1-12 are directed to a process for identifying candidate molecules by comparison of molecular fields. The following analysis is taken from the guidance provided in the MPEP at 2104.IV, "Determine Whether the Claimed Invention Complies with 35 USC101". The claims are directed to processes. Here the claims are directed to

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the abstract idea of quantifying the similarity between two molecules by comparing derived mathematical predictions of the fields representing the molecules. The processes do not recite a physical transformation of matter from one state to another. Giving the claims the broadest reasonable interpretation, the claims read on mental steps. In *Comiskey* (*In re Comiskey*, 84 USPQ2d 1670) the court established that “the application of human intelligence to the solution of practical problems is not and of itself patentable” (at 1680). In *Comiskey*, the court stated explicitly “mental processes - or processes of human thinking - standing alone are not patentable even if they have a practical application” (at 1679). The court in *Comiskey* stated, “Following the lead of the Supreme Court, this court and our predecessor court have refused to find processes patentable when they merely claimed a mental process standing alone and untied to another category of statutory subject matter even when a practical application was claimed” (at 1680). The court’s recent decision in *In re Bilski* confirmed, “a process is patent-eligible under 35 USC 101 if it is tied to a particular machine or apparatus or if it transforms a particular article into a different state or thing” (*In re Bilski*, 88 USPQ at 1391, 2008). In the instant claims, the process is not tied to a class of statutory invention. Claims 1-12 recite providing an output or a response to a user. The output is insignificant post-solution activity and does not represent a significant tie to another category of invention. The court in *Comiskey*, stated, “the court rejected the notion that mere recitation of a practical application of an abstract idea makes it patentable, concluding that ‘[a] competent draftsman could attach some form of post-solution activity to almost any mathematical formula’” citing *Flook* (437 U.S. at 586, 590). The

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recent decision in *Bilski* confirmed the court's position regarding insignificant pre- or post-solution activity (i.e. insignificant extra-solution activity) as stated in *Comiskey* (see *In re Bilski*, 88 USPQ2d 1385 (Fed. Cir. 2008) at p. 13-96-1397). Applicant is encouraged to consider the recent BPAI informative decisions *Exparte Langemyr* (No. 2008-1495 (28 May 2008)) and *Exparte Biliski* (No. 2002-2257 (26 September 2006)) for further clarification of the above grounds of rejection.

Response to Arguments

Applicant's arguments filed 03 November 2009 have been fully considered but they are not persuasive. Applicant argues the claims as amended transform field point data into a score and thus satisfies the machine or transform test put forth by the CAFC in the *In re Biliski* decision. The argument is not persuasive. The claims are directed to the mathematical manipulation of data from one form to another. The court in *Bilski* indicated rather clearly that a patent eligible transformation "transforms a particular article into a different state or thing" (*In re Bilski*, 88 USPQ at 1391, 2008). In the instant case, no such transformation is taking place. The rejection is maintained

Claim Rejections - 35 USC § 112

Response to Arguments

The rejection of claims 1-13 and 16 under 35 USC 112, second paragraph is withdrawn in view of the amendments to the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The following rejections are new.

Claim 1-13 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is directed to a process in which a set of field points, each having position and a field size value, for a molecule having a known activity are provided; at the position of the field points of the first molecule, the field of a second molecule are determined to produce field sample values; the field sample values are combined with the field size values to provide a score of similarity; and a measure of the second molecule to have the activity of the first molecule is provided from the score.

Claim 1 is unclear with respect to the term "field". The lack in clarity makes the metes and bounds of the claim indefinite. The claim does not distinctly indicate what a field is. Furthermore, the claim provides no indication of whether the field of the first molecule is the same field as the field of the second molecule.

Claim 1 is further unclear with respect to the relationship between the field sample values and the field size values. The metes and bounds of the claim are rendered indefinite by the lack in clarity. The claim does not distinctly point out what the relationship is between the field sample values and the field size values. The ambiguity in the relationship between the field sample values and the field size values. Claims 2-13 and 16 are also rejected because they depend from claim 1, and thus contain the above issues due to said dependence.

Claim 5 is unclear with respect to the term "absolute field size value". The metes and bounds of the claim are rendered indefinite by the lack of clarity. The specification

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reveals at p. 10, line 11-13 that “the scaled field size values have the magnitude of the square root of the absolute field size values”. The specification does not describe what the “absolute field size values” are. At p. 16, line 9, the specification similarly recites the “absolute field value” but exemplifies the determining the square root of the absolute value of the field value. If applicant intended to the term “absolute field size value” to refer to the absolute value of the field size value, then it may appropriate to amend the claim to recite the phrase “absolute value of the field size value”.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following rejection is new.

Claims 1-13 and 16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for electrostatic fields, does not reasonably provide enablement for any field. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

In *In re Wands* (8 USPQ2d 1400 (CAFC 1988)) the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be considered in a determination of "undue experimentation." These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the

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invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims.

In considering the factors for the instant claims:

a) In order to use the claimed invention one of skill in the art must perform a process in which a set of field points, each having position and a field size value, for a molecule having a known activity are provided; at the position of the field points of the first molecule, the field of a second molecule are determined to produce field sample values; the field sample values are combined with the field size values to provide a score of similarity; and a measure of the second molecule to have the activity of the first molecule is provided from the score. For the reasons discussed below, there would be an unpredictable amount of experimentation required to practice the claimed invention.

b) The description describes a process in which the extrema of a particular field of a first molecule is overlaid on the same type field of a second molecule and is scored. The description further describes molecular field types as electrostatic, surface interaction, and hydrophobic (p. 3). The description does not provide detailed guidance to the determination of a overlay score between a first and second molecules from any field of the first molecule and any field of the second molecule.

c) The description provides working examples of overlaying the electrostatic field extrema of a first molecule on the electrostatic field of a second molecule to determine a score. The description does not provide working examples of overlaying any field of a first molecule with any other field of a second molecule.

d) The nature of the invention, molecular modeling, is complex.

e) The prior art does not show overlaying any field of a first molecule with any other field of a second molecule. The prior art shows the comparison of fields of identical type. Maggiora et al. (Journal of Mathematical Chemistry, Vol. 31, No. 3, p. 251, 270, April 2002) shows the comparison of the electron density, viewed as a steric field, of a first molecule to the electron density of a second molecule to derive a score of similarity (p. 252). Additionally, Maggiora et al. shows the comparison of the electrostatic fields between a first and second molecule. Maggiora et al. shows that a plurality of fields comparisons are performed and can be weighted, summed, and presented as a combined index (p. 253). Maggiora et al. does not show that a field of a first molecule is compared to a second field of a second molecule.

f) The skill of those in the art of molecular modeling is high.

g) The predictability of a score between the field extrema of a field of a first molecule and any field of a second molecule is unknown in the prior art.

h) The claims are broad in that the field extrema of a field of a first molecule is used to determine of a first molecule to which is compared any field of a second molecule.

The skilled practitioner would first turn to the instant description for guidance in using the claimed invention. However, the description lacks clear evidence that a score between the field extrema of a field of a first molecule and any field of a second molecule can be produced. As such, the skilled practitioner would turn to the prior art for such guidance, however the prior art does not discuss a score between the field extrema of a field of a first molecule and any field of a second molecule. Finally, said

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practitioner would turn to trial and error experimentation to determine a relationship between the two molecules from a score between the field extrema of a field of a first molecule and any field of a second molecule. Such amounts to undue experimentation. Claims 2-13 and 16 are also rejected because they depend from claim 1, and thus contain the above issues due to said dependence.

Claim Rejections - 35 USC § 103

Response to Arguments

The rejection of claims 1-3, 6, 11-13, and 16 as unpatentable over Mestres et al. in view of Vinter et al. and in view of Apaya et al. under 35 U.S.C. 103(a) is withdrawn in view of the arguments presented.

The rejection of claims 7-10 as unpatentable over Mestres et al. in view of Vinter et al. and in view of Apaya et al. and in further view of Maggoria et al. under 35 U.S.C. 103(a) is withdrawn in view of the arguments presented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KARLHEINZ R. SKOWRONEK whose telephone number is (571)272-9047. The examiner can normally be reached on 8:00am-5:00pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/KARLHEINZ R SKOWRONEK/
Examiner, Art Unit 1631

4 March 2010